INTERIM REPORT - UPPER OTTAWA STREET LANDFILL SITE STUDY, REFERENCE PAPER 26 : FEASIBILITY ASSESSMENT OF HEALTH STUDIES.

REFERENCE 26

FINAL REPORT

OF THE

FEASIBILITY ASSESSMENT

OF

UPPER OTTAWA STREET

LANDFILL SITE

HEALTH STUDIES

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PART I:

REPORT ON FEASIBILITY STUDY

REPORT ON FEASIBILITY STUDY

Introduction: A feasibility study has been conducted to assess how the health effects of the Upper Ottawa Street landfill site could be investigated. This study was recommended by the Health Advisory Group to the Upper Ottawa Landfill Project Committee. The committee reviewed the recommendation and endorsed the suggestion. Dr. Harper was asked to prepare the proposal which was submitted in October, 1981 to the Ministry of Health. Funding was approved for a six month period starting in November, 1981.

This document reports the work done in the feasibility study including recommendations for research.

The aim of the feasibility study was to assess the feasibility of epidemiological investigations of the health impact of Upper Ottawa Landfill Site on site workers and local residents. The study was to address the feasibility of examining:

i) The effect upon current health status, and
ii) The effect upon long-term health status, and
iii) The effectiveness of an intervention to reduce the current health concerns of residents.

The Health Advisory Group has identified a number of possible studies which could contribute to understanding the health effects of the landfill. Of these studies four were considered of particular relevance. These were:

#1: A comparative analytic survey of landfill site workers;
#2: A comparative analytic survey of residents;
#3: A cohort study of residents and non-residents;
#4: A randomized controlled trial.

Each of these studies were evaluated in the feasibility study.

The study provided financial support for a reasearch associate full-time and a half-time secretary, both for six months.

Progress was reported at regular intervals to the Health Advisory

Group and the Committee throughout the study period. In December an estimate of expenses for the 1982-1983 financial year was submitted to the Committee. In January a progress report was submitted describing work done and an outline-proposal for a comparative survey of residents which included a medical examination. In February the January-proposal was described to a meeting of residents at their request. A document entitled "A strategy to assess the health effects of the Upper Ottawa Street Landfill Site" was submitted and presented to the Committee on April 1st, 1982. This document contains the results of the feasibility study.

Method: One of the initial tasks was to assess the feasibility of the four studies mentioned above. The results of this stage of the work will be described first and then some general problems which were identified will be described.

Review of Specific Study Designs

A comparative analytic survey of landfill site workers was considered for several reasons. Worker studies have been the major source of scientific information on the human health effects of harmful substances and, therefore, a worker study was considered to have the greatest likelihood of providing important information. If such a study included all provincial landfill site workers it would benefit the province as well as those affected by the Hamilton site. In terms of feasibility, the longer lapse in time since initial exposure among site worker than among the majority of residents would give a worker study a greater likelihood of demonstrating a harmful effect, at an earlier date, than would a study of residents.

It was found that despite the large number of dumps and landfill sites in the province there was no accurate classification of what substances were deposited in them. This is of considerable importance epidemiologically because nearly all harmful substances produce specific effects which differ from substance to substance and which may not be easily detectable even within individuals exposed to the same substance. The detection of adverse

health effects among workers, who vary greatly in degree and type of exposure, is probably not possible with routine epidemiological methods. It is, therefore, necessary to be able to identify workers who have the same type and amount of exposure. Unfortunately, from a research point of view, many dump and landfill workers do not limit their work to one site, rather they work at more than one site concurrently. For these reasons a province wide study of workers was considered infeasible.

However, a study of the landfill site workers in Hamilton does appear to be a feasible project. While these workers worked at all three Hamilton dump sites, it was only the Upper Ottawa site which was used for industrial wastes. The numbers of workers identifiable is small, however, forty-three names and addresses have currently been identified. The difficulty in studying such a group is that only large health effects can be shown to be statistically significant.

The main advantage of a worker study would be its potential to investigate long-term health effects such as cancer.

A comparative analytic survey of residents on the other hand can only define short term health effects due to the short period of time since initial exposure. Physical health effects other than nerve toxicity, cancer, liver disease and lung disease tend to be of short duration and to occur during peak exposure. Assessment of physical health following exposure and prior to the onset of malignancy is not likely to identify abnormalities. Psychological effects and attitudinal changes may be apparent however. Beyond the consideration of the effect which a residents' survey could identify, based on current knowledge, is the issue of providing maximal service and reassurance to the residents.

A questionnaire survey of residents' reported health would provide an effective means of identifying current health problems given that a physical examination is unlikely to identify problems which are not producing symptoms. It also needs to be recognized that the residents consider themselves to have experienced excessive health problems because of the landfill site and a small survey conducted by the residents was consistent

with this. A systematic verification of reported health would seem to be justified and failure to conduct such a survey could possibly provoke criticism from the residents.

In addition to a questionnaire survey of residents is the possibility of a study involving a medical examination. This is a far more complex issue to address.

The possible health effects of exposure to industrial chemicals from a landfill site are not limited to substances originating from the landfill. Toxins such as heavy metals, alcohol, pesticides and cigarette smoke are general environmental contaminants. These other sources are usually of far greater importance than local sources of pollution such as that originating from a landfill site. The first problem to overcome in a medical examination study is distinguishing between effects from the landfill site and those effects from other sources. One of the most important ways to overcome this problem is to identify the particular toxin in question and to design the study to detect the particular toxic effect which is specific to that toxin. This approach is therefore dependent upon added information on the chemical nature of the pollutant to which residents have been exposed. This interdependence of different studies is an important characteristic of the investigation of the health effects of landfill sites. It will be returned to in depth in Part II of this report.

A further problem with a medical examination study concerns the interpretation of laboratory investigations. Laboratory tests are well known to have a wide variability due to both natural biological variability and lack of consistency of the laboratory measurements. Furthermore, body levels of heavy metals, PCB's, and pesticides have been shown to be high in general populations due to general pollution to which large sectors of society are exposed. These problems make the interpretation of laboratory findings very difficult, reduce one's confidence in their importance but also provide relatively concrete information which can be used to support an argument either for or against the harmful nature of a landfill site. In the view of the authors' data which does not add clarity to the problem

should not be gathered at all.

For these reasons a medical examination should not be part of this scientific investigation.

This is not a reason, however, to withhold medical assessment from the residents when this is offered as a medical service. There is probably good reason based upon the public concern engendered by the landfill site problem to offer a special medical assessment to residents. The results of this should not form part of the scientific investigation.

A cohort study of residents is the type of investigation which is capable of providing the most information. In this situation, however, such a study would need to continue for approximately twenty years from the time of exposure in order to identify the effect upon cancer incidence. Such a study would be of possible greater benefit to future generations than to the residents in the study.

However, even this highly effective epidemiological method has limitations. Its efficiency depends upon the accuracy with which the exposed individuals can be identified. Inadvertent inclusion of unexposed individuals in the exposed group could render the study useless to the point of providing false results. In the same vein, if exposure levels are very low and the true effect is small, then this effect may not be detectable.

While the cohort design is generally very useful its role and utility in the case of the Upper Ottawa Landfill problem cannot be assessed until the chemical content of the site and the exposure of individual residents to these chemicals is known.

A randomized controlled trial was proposed by the Health Advisory Group as a possible strategy because of interest in assessing a method to help relieve the apparent anxiety and apprehension experienced by a proportion of residents.

One of the peculiarities of the landfill problem compared with other public health problems is the lack of information describing increased

sickness. The problem is predominantly a concern about the risk of a health problem and not concern about an already identified illness. It is important to recognize this distinctive feature and to adapt one's approach to it accordingly.

Before a solution can be tested it is obviously necessary to define the problem. A randomized trial may or may not be indicated. This decision needs to be made once more information of a descriptive nature has been gathered.

Discussion: Upon review of the different research approaches it became clear to us that the investigation of the health effects of the landfill site needed to be a stepwise process. A research strategy which integrates information from different aspects of the overall problem was considered necessary. This strategy would need to start with a descriptive phase in which a more complete definition of the health problem would be made. Depending upon the results of this first phase the subsequent steps would be designed. The two dimensions to the initial descriptive phase require to include an assessment of evidence about the potential health risk for individuals exposed to the landfill site. The second dimension is the assessment of exposure of individuals to the content of the site; a false assumption of exposure can negate even the best research efforts.

This strategy has, therefore, been written and forms Part II of this report. In it are proposed three parts to the health investigation. The first is a synthesis of five categories of investigation upon which an assessment of the likelihood of a health risk can be made. This is the largest and most expensive part of the proposal. The second is the assessment of exposure of residents to pollutants originating from the site. The final stage is the long term follow-up of individuals to investigate the effect of exposure upon death rates and cancer and other disorders. This stage is, however, directly conditional upon the findings of the first two stages.

The most important issue, from a public health standpoint, is

whether or not there is evidence of a health risk and whether further investigation is justified. At this time there does not seem to be adequate information to decide upon the importance of the landfill site as a health hazard. Once the question of the importance of the problem is answered to the best of our ability, it is necessary to know whether a long term investigation is feasible. This will depend to a large degree upon whether or not the exposed individuals can be identified. The decision to conduct a long term follow-up study will only be made when the importance of such a study and its feasibility have been assessed.

Conclusion:

A feasibility study has been conducted and reported upon. It is recommended that steps be taken to implement the research strategy described in Part II of this report. These steps are listed below:

(1) Develop the questionnaire protocol (Part III) in those aspects concerning the medical assessment, the instrument and the interviewing procedure.

(2) Develop a worker study protocol.

(3) Obtain a veterinary epidemiologist consultation to assess the feasibility of the animal studies; review his recommendations and plan an animal study accordingly.

(4) Define the anticipated procedure for incorporatng the chemical analysis results into the strategy.

(5) Define the procedure for reviewing the question of toxicity assessment of the important chemicals.

(6) Design the study for assessing exposure of individual residents.

Of the above tasks (1), (2), and (3) should be given priority. For details on these tasks it is necessary to refer to Parts II and III.

In conclusion the general problem of the health effects of the Upper

Ottawa Landfill Site is an important public health concern for which a specific research strategy is indicated. The strategy is one which on the one hand provides maximum protection to residents while providing a mechanism to avoid expensive, ineffective, and possibly harmful over-investigation in those circumstances where investigation is either not feasible or injustified.

It is hoped that the proposed strategy will be considered as a single entity and that its components will not be considered in a piecemeal fashion.

PART II:

A STRATEGY TO ASSESS

THE

HEALTH EFFECTS

OF THE

UPPER OTTAWA STREET LANDFILL SITE

A. Summary

A stepwise approach to the evaluation of the health effects of a landfill site is described. The many unknowns concerning landfill sites preclude a single-stepped investigation. Three stages of investigation are described without committment to necessarily proceeding to the third stage. Several studies are proposed within the framework of the strategy to address the questions:

1. Is there evidence of a health risk?
2. Is there evidence of exposure?

And, if indicated by either or both of the first two,

3. How should a definitive study be conducted?

It is suggested that the strategy provides maximum protection to the residents, has built-in controls to avoid doing more than is scientifically justifiable, and should do more good than harm. Based on these considerations, the strategy is proposed as being worthy of critical review as a methodology for assessing the health effects of point sources of pollution.

B. Introduction

The Upper Ottawa Street Landfill Site was closed in October 1980 having been in operation for over thirty years. It was used for domestic, commercial and industrial wastes which included an estimated five million gallons of liquid industrial waste annually during the mid 1970's.

Local residents expressed concern for their health due to their proximity to the landfill site. One resident conducted a survey of 127 local residents and 134 residents from another area. The residents near the site reported an excess of a variety of health problems over the control group. In October 1980 the Ontario Minister of Health responded to the calls for an inquiry into the dump and ordered a full scale study to be funded by the Ministry.

Apart from the residents' survey there has been no documentation of a health problem. In addition, the chemical composition of the site remains poorly defined. This will be known however upon completion of a current study. Environmental studies have been conducted of water, soil and air which have not provided consistent evidence of hazardous levels of pollution.

At the time of writing the problem to be addressed is one of an unsubstantiated health hazard. Three components of the problem are unsubstantiated:

(i) the nature and concentration of the suspected chemicals;
(ii) the level of exposure experienced by residents to these chemicals and,
(iii) whether adverse health effects have occurred in the exposed residents or whether their health will be affected in the future.

The purpose of this paper is to present a strategy for investigating the health effects of the Upper Ottawa Street landfill site upon human health.

The question to be answered can be expressed simply as:

"Has the dump caused ill health?"

Subsumed within this question, however, are several inter-related and sequential questions, each of which contribute a necessary step towards arriving at the final answer. These specific questions are:

(i) What is the concentration of toxic chemicals in the dump?

(ii) Have residents been exposed to these chemicals?

(iii) Has the dump increased the residents' expected level of exposure beyond the level expected in the general population?

(iv) Is the occurrence of ill health in the exposed residents in excess of that expected in the general population?

(a) in terms of illness known to result from the identified chemical exposure?

(b) in terms of other illness?

The relevance of each of these questions depends upon the answer to the one preceeding it. For example, question #iv is relevant when high concentrations of toxins are present in the dump and residents have been exposed to these chemicals at a level exceeding exposure of the general population.

Justification of an investigation of health effects in the exposed population can therefore be made on the basis of documented toxic exposure originating from the dump. The inferences drawn from a health investigation will depend upon both the findings of the chemical analysis of the dump and of human exposure. There is, therefore, an inferential dimension to the justification of a definitive health study.

Definitive evaluation of the health effects will in all likelihood require a prospective follow-up study (1) for a time period which is long enough to allow adverse health effects to manifest themselves. Cancer is one of the primary outcomes of interest which generally has a latent period of approximately twenty years between the time of exposure and appearance of the malignancy. For the dump residents, the majority of whom have lived near the dump since the late 1970's, such a study would need to continue until the late 1990's before a definitive answer could be obtained. As implied above, given the causative nature of the inquiry it is necessary to substantiate the link between the observed health effects and chemical exposure which has arisen from the dump. Therefore individual residents enrolled in such a follow-up study need to meet accepted criteria of exposure. Similarly the particular chemical exposure must have been shown to have arisen from the dump and not from another source. If these conditions are not met then a positive

result cannot be confidently attributed to the dump and a negative result may be interpreted to indicate that either the wrong group was studied or the dump presented no risk to health. Such inconclusive results should obviously be avoided.

In addition to the inferential aspect of justification for a definitive health study there is the more basic question of the current indications of the dump presenting a health risk. To date the evidence concerning the existence of a health problem due to the Upper Ottawa Street dump is limited to the residents' survey. Justification in terms of evidence of possible health effects is important for several reasons. From a practical standpoint both the assessment of residents' exposure and the implementation of a definitive study depend upon the participation of large numbers of individuals who deserve to know why they have been asked to participate. Secondly, there are limitations to our knowledge of the toxic effects of chemicals and to the measurement of known toxins in body tissues and fluids. Careful appraisal of current evidence of the health of any exposed individuals will reduce the likelihood of missing unanticipated health problems. Thirdly, there is public responsibility. Chemical production, usage and disposal is now ubiquitous within industrialized nations. Investigation without substantiation of a health problem will confuse the public and set a precedent for investigation on minmal evidence. Such expenses should be reserved for the circumstances when there is indication that a health problem exists.

In broad terms there are three components to the question of investigating the health effects of the Upper Ottawa Street dump. The first is justification of a definitive study in terms of current evidence of a health problem. The second is justification in terms of documenting exposure. Third is the question of the design of the definitive health study.

The feasibility and planning of a health study revolves around these three questions and therefore each one will be considered in turn. The three questions are:

1. Is there evidence of a health problem?
2. Is there evidence of exposure?
3. How should a definitive study be conducted?

C. Justification for a definitive health study

Society at large is exposed to greatly increased amounts and types of chemicals than it was forty years ago (2). However, this has not led to any observed increases in cancer in the general population which can be attributed to this cause (3). The lung cancer epidemic is explained by an alternate hypothesis (3). While air pollution in extreme form causes a greatly increased death rate at the time of the pollution as witnessed in the 1952 London fog, the effects of air pollution on lung cancer have been undetectable epidemiologically (4,5,6). Extrapolation from incidence rates among highly exposed groups have however attributed some degree of increased risk of lung cancer to air pollution from benzopyrene (7), arsenic (8), asbestos (9) and radiation (10).

Point sources of chemical pollution, excluding occupational exposure accidents and disasters, have been suspected of causing adverse health effects but this has not been substantiated. In instances where exposure to specific chemicals has been established these chemicals have been identified in human fluid samples (11). Transient elevations in liver enzymes have also been documented (11). The long term health effects of these exposures is not known. Cytogenetic analyses have been shown to be affected by low dose exposures but there too the long term health effects are not known (12,13). Studies of health effects have not been sufficiently rigorous from the methodologic standpoint to allow confident interpretations of findings (14,15). Reproductive health effects are of particular interest but studies of the effects of low chemical exposure upon these outcomes "are few and often are unsatisfactory" (16).

There is however much evidence of human toxicity from specific chemicals derived primarily from the study of high and long term occupational exposure. These are presented in Table 1.

Table 1: Established occupational causes of cancer

Agent	Site of Cancer
Aromatic animes	Bladder
Arsenic	Skin and lung
Asbestos	Lung, pleura and peritoneum
Benzene	Bone marrow
Bischloromethyl ether	Lung
Cadmium	Prostate
Chromium	Lung
Ionizing radiations	Bone, lung, marrow
Isopropyl oil	Nasal sinuses
Mustard gas	Larynx, lung
Nickel	Lung, nasal sinuses
Polycyclic hydrocarbons	Skin, scrotum, lung
U.V. light	Skin
Vinyl chloride	Liver and nasal sinuses

adapted from Doll and Peto (17)

Several points of note concerning these data are of particular interest and relevance. First, the toxic effect of a given chemical is specific for a given type of cancer. Second, these findings have come from studies of occupational groups in whom the exposure was well defined and generally far in excess of exposure to the general community. Third, while adverse outcomes have been identifiable in studies of occupational groups exposed to toxic chemicals some of these relationships have been shown not to be detectable in epidemiologic studies. A striking example is the case of air pollution by polycyclic hydrocarbons and lung cancer. Despite lifelong differences in exposure to air pollution in Finland and Britain, and similar cigarette consumption, "the lung cancer mortality among people who had been young between the two wars has been almost identical in recent years" (18). Other examples of epidemiologic methods being unable to identify adverse effects from substances known by other methods to be carcinogenic have been furnished by Hammond and Garfinkel (19) and Kinlen et al (20) and Hennekens et al (21). The latter two are studies of permanent hair dyes which although are not shown conclusively to be carcinogenic in these epidemiological studies have been

found to be mutagenic on Ames testing and to be carcinogenic in animals (22).

The literature does not provide an indication either for or against the existence of health problems among individuals residing in the proximity of an industrial chemical landfill site. It is beyond dispute however that given chemicals in sufficient doses can cause cancer and that this has occurred primarily among occupational groups. Despite contamination of local environments around dumps and the environment in general, the evidence suggests that the concentration of chemical pollutants is generally very small and any health effects have as yet gone undetected.

This information combined with what is currently known about the health effects of the Upper Ottawa Street dump do not provide strong evidence that a health problem exists or is likely to develop in the future. For this reason it is necessary to conduct specific investigations to determine whether a potential problem exists.

Methodologically the investigation of health effects of landfill sites is a complex and slow process about which views vary. There are, however, a number of methodological principles which can be identified.

(i) Specificity of outcome to exposure:

Health effects of toxic chemicals tend to be specific to the type of chemical (23). This is of central importance to investigating health effects of toxic exposures. First it is strongly stated by many authors that the exposure of the subjects being studied should be measured precisely (24,25). It is not enough, however, to use environmental contamination as a surrogate for human exposure as it has been demonstrated that even when the environment is heavily contaminated individuals may avoid exposure (26). For this reason it is necessary to assess exposure at the individual and not group level (27). In terms of outcomes it is important to be specific and to avoid multiple outcome measures (28). With multiple outcomes some will be positive through chance alone and the great difficulty of interpreting these results is then created. Although a positive outcome due to chance is statistically considered to be "not significant" the possibility of such an outcome being considered "suspicious" cannot be avoided once the data has been produced.

(ii) Who to study:

Controlled investigation is fundamental to this (29) and any scientific inquiry. The study subjects should be selected individually on the basis of exposure (27). The question of controls is made very difficult by (1) the presence of many sources of chemical exposure in addition to exposure due to the landfill site and, (2) by the lack of a normal level of exposure in the general population (29).

(iii) Type of study:

This subject is one which is truly multidisciplinary (30) and the answer should be sought through employing a diversity of research approaches. The Ames test can rapidly and relatively cheaply evaluate the mutagenic effects of a given chemical (31). Animal studies, both wild and domestic (32) animal studies in their usual environment and animal experiments, can play an important role (33,34). Given the long latency period for cancer to develop in man and the short period in animals the investigation of carcinogenesis in animals can provide evidence in one or two years compared with twenty years of follow-up in man. Occupational groups tend to have exposures far in excess of the general population. If adverse effects do not occur in these groups then there is very little likelihood of other groups being adversely affected. Studies of occupational groups are probably the best indicator of a health effect. Follow-up studies are the definitive method to establish that a causal relationship exists. There are, however, some major practical limitations to such studies (35). They take many years to complete and they depend upon continued follow-up of the study and control groups in order to provide an answer.Compliance is a major consideration. Prospective studies are expensive. Furthermore, the right group must be identified at the outset and this depends upon precise assessment of exposure. A less time consuming research design is the case-control method. This has proved most productive in studies of occupational disease of which there are innumerable examples. However the higher exposures experienced by occupational groups and ready hypotheses concerning specific disease outcomes make this method feasible. Its application to investigating low exposures from dump sites has not yet been demontstrated.

(iv) Statistical difficulties:

A small number of specific outcomes which occur frequently presents a manageable task from the statistical viewpoint. The landfill site problem is commonly one of numerous possible outcomes of infrequent occurrence. Feasibility of study designs therefore relate to the extent to which the researcher can refine his research question to investigate as few outcomes as possible among individuals who are at greatest risk of developing the outcome.

(v) An approach to the methodologic problems:

Given the very considerable methodological difficulties of investigating the health effects of exposure to landfill sites, a specific methodological strategy is required. Based on the experience and writings of a number of scientists in the field the following strategy has been designed (3,11,13,16, 24,25,28,31,32,1).

D. A Strategy to Assess the Health Effects of the Upper Ottawa Street Landfill Site

The proposed strategy is designed, on the one hand, to provide the maximum protection to the residents in the vicinity of the Upper Ottawa Street site and, on the other hand, to avoid unwarranted investigation. The present situation is such that investigation beyond what has already taken place is indicated. It is proposed by the authors that the investigation which will efficiently and scientifically assess the health effects of the dump is the following.

The strategy has three stages which should be addressed in sequence. In each stage a specific question is to be answered. The three stages address the following questions:

Stage one: Is there evidence of a health risk?
Stage two: Is there evidence of a significant level of chemical exposure?
Stage three: Is a definitive health study indicated?

Each stage comprises several investigations.

1. Stage one: Is there evidence of a health risk?

Existing data has been unable to adequately answer this question and therefore there is a need for further empirical evidence.

In order to answer this question by means other than a long term follow-up study there are several relatively short term and relatively inexpensive investigations designed to provide indirect evidence of whether or not a health problem exists. The aim of these investigations is to provide evidence of sufficient scientific validity on which to base the decision of whether to proceed with further studies or to discontinue investigation. These investigations have been identified such that a negative result would be accepted as sufficient evidence of there not being a significant increase in health risk. Alternatively, if these investigations show a positive result the indication of a possible health problem is sufficiently strong to justify and necessitate further investigation.

Study #1: Chemical analysis of the dump

Aim: The aim of this study is to define the type and concentration of toxic chemicals within the dump and in leachate migrating from the dump.

Feasibility: This study is already in progress.

Relevance: This analysis is of importance because of the dependence of subequent investigations upon its results. These results will provide the necessary information for the following:

(i) to know which chemicals to investigate for toxicity

(ii) to know which chemical exposures to evaluate in the residents

(iii) to know which health effects to look for, and finally

(iv) to link health effects to the dump.

Study #2: Ames testing of selected chemicals

Aim: The aim of these tests is to determine the toxicity and mutagenicity of the dump chemicals

Feasibility: Such testing is designed to be an efficient method to evaluate many chemicals at reasonable expense in short periods of time. Many chemicals will not have undergone such testing, there will be some which have been tested however.

Interpretation: Ames test negative chemicals can be considered to be less likely to be carcinogenic than Ames test positive chemicals. Further study by other methods should be considered for the Ames test positive chemicals if present in significant concentrations.

Relevance: The Ames test provides a method of screening chemicals into those which are potentially carcinogenic and those which are not likely to be carcinogens. This provides an important guide for subsequent studies allowing investigation to be focussed on the potentially harmful chemicals.

Study #3a: An observational study in domestic and wild animals

Aim: The aim would be to answer the following question: Has there been an increase in cancer among either wild or domestic animals which live in the vicinity of the dump?

Method: The method would involve the cross-sectional survey method in which a large proportion of the existing population would be examined for the presence of cancer. An estimate of death rates among domestic animals could be obtained through a questionnaire survey of pet owners. This could be done in conjunction with Study #5.

Feasibility: Domestic animals could be readily identified and permission for assessment would then need to be obtained from the owners. This may or may not meet with high compliance. The method would depend upon the accuracy of diagnosing cancer in animals without invasive techniques. Wild animals present a different problem in terms of identification which the zoologists would need to assess for feasibility.

Animal studies are, however, an excellent method of assessing carcinogenicity because of the short time period required between exposure and development of the malignancy.

Interpretation: Given the presumably greater exposure in wild animals than in humans a negative result would be an important indication of there not being a health problem. A positive result on the other hand would demonstrate that the dump is capable of causing cancer and therefore it may be capable of causing cancer in man.

Relevance: A valid negative answer is important evidence against the dump being harmful.

Study #3b: Experimental exposure in animals

Aim: The aim would be to answer the following question: What is the carcinogenic dose response effect of specific chemicals in laboratory animals?

Method: The research design would be a randomized controlled laboratory animal trial of specific toxic chemicals.

Feasibility: The specific chemicals in question require to be identified. With this information such experiments can be implemented and would take up to two years to complete, but at considerable expense per each chemical.

Relevance: This study would provide specific dose-response data which is not obtainable from the observational animal study. Depending upon the chemical analysis of the dump this study may be found to have been done already. This study would be indicated if cancer was detected in the observational animal study, but would not be indicated if a valid negative answer was obtained.

Study #4a: Upper Ottawa Street Landfill Site Workers Study

Aim: The aim of this study is to detect whether there has been an increase in: (i) major health endpoints such as cancer or death, and (ii) health services utilization among the landfill site workers.

For exploratory purposes data would also be gathered on exposure, additional health outcomes and reported health.

Method: The design would be a comparative historical cohort study. The Upper Ottawa Street landfill site workers would comprise the study group; controls would be selected, at least at a 2 to 1 ratio, from matched outside workers not exposed occupationally to industrial or agricultural chemicals or waste chemical dumps.

Feasibility: The first feasibility question concerns the identification of the dump site workers. Of the 19 garbage pickers registered in January 1966, 11 were still registered in 1974. The names and addresses are available for both dates. There were no new garbage pickers since 1966. In addition, 19 city and regional employees have been currently identified as having worked at the site as supervisors, equipment operators, and scale men. The names and addresses of these men as of 1980 are available. It is anticipated that additional employees will be identified, the total number is estimated to be 25.

The second concern is whether there are adequate numbers available from a statistical point of view. It is estimated that with 44 workers, and alpha set at 0.05, beta at 0.10 in one-tailed tests, this study would be able to detect a 3.2 fold increase in deaths or in health services utilization.

Interpretation: A negative result in this study will provide strong evidence that the dump does not present an unusual health risk given no new mode of exposure.

A positive result in this study will indicate that the dump can present a health risk for individuals exposed in the same manner and to the same degree as the dump workers. Such a result, however, does not indicate that the health of residents has been affected.

Relevance: A negative result would support the decision not to proceed further with health studies unless modes of exposure other than physical contact and inhalation are identified. A positive result would need to be interpreted along with other data. A positive result plus an identified route of exposure to another cohort would strongly influence the decision to proceed with detailed study of that cohort.

Should further investigation be indicated, the workers' study would yield background data, indicators of exposure and outcomes required for additional study.

Study #4b: A study of other workers exposed to the same chemicals as exist in the Upper Ottawa Street dump.

Aim: The aim of this study is to assess whether workers exposed to chemicals of the same nature as have been identified in the Upper Ottawa Street dump and who work elsewhere have an excess of health problems.

Methods: Such a study could be an historical cohort design which could be analysed by both proportional mortality ratios and standardized mortality ratios.

Feasibility: The feasibility would depend upon the availability of workers exposed to the chemicals of interest without contamination from additional toxic substances. This problem could interfere with such a study, however this cannot be assessed until the chemical composition of the dump is definitely identified.

Study #5: Questionnaire survey of residents' reproted health

Aims: (1) To systematically evaluate a problem which has been identified, and reported in parliament, by some local residents.
(2) To identify whether residents in the vicinity of the dump report an excess of health problems.
(3) To determine whether reported health problems are associated with proximity to the dump or duration of residence in the area.
(4) To define qualitatively the types of health problems reported by residents and individuals who do not reside in the vicinity of the dump.

Methods: The design is a comparative cross-sectional survey of a stratified random sample of local residents and a matched control group. The study population will be defined from the 1980 property tax assessment. Data will be gathered by interview and a self-administered questionnaire. The sample size required is 1150 per group; see Part III.D.5.d. for details.

Clinical Assessment: Questionnaire data will be collected on all individuals residing within 500 metres of the current perimeter of the landfill mound and on a random sample of those residing within 1 kilometer, as well as on the comparison group. The family physician identified by each respondent will be informed of the results, and may, in consultation with the resident, decide

whether clinical assessment or referral to a specialist is warranted.

By this mechanism all study participants will be screened by the health questionnaire and will be given full opportunity for a complete clinical assessment. Procedural details for this referral system are included in Part III, Appendix B.

Feasibility: The data exist to allow selection of study subjects. Experience of such surveys is suffucient to indicate that this is a feasible method of investigation. It does not present undue demands of the subjects and it involves no unusual ethical issues. Special strategies to control biased reporting and interviewing will need to be employed. This study will take approximately 18 months to complete.

Interpretation: A positive result will indicate that either an attitudinal or emotional health problem exists or there is a physical health problem. If a positive result is accompanied by negative results from studies 3a and 4a the interpretation would be that the problem is unlikely to be a physical health problem which could be diagnosed by clinical assessment.

If, however, a positive result is accompanied by positive results in studies 3a and 4a further consideration of the possibility of a physical health problem is indicated.

A negative result would indicate the absence of an attitudinal or emotional problem. It should not be employed to address the question of physical health other than to indicate that the likelihood of finding abnormal physical signs is reduced when the medical history is negative.

This study will allow the magnitude of the perceived problem to be defined. It will also define the nature of the problem.

Relevance: This study will provide a factual basis to public opinions. It will help decipher the attitudinal dimension to the problem. It will help decide upon subsequent action and pro-

vide important personal and attitudinal data on which to base the decision.

It provides for a clinical assessment which respects the patients' choice of personal physician while offering the best opportunity for the highest quality of care through the information provided to the physician and identification of specialists prepared to consult in the field of toxicology.

The protocol for this study is attached as Part III of the feasibility report.

These studies fulfill all the steps included in stage one. It is important to re-state that these first steps are designed to identify whether there is <u>any indication</u> of toxicity associated with the landfill. The aim is not to verify or refute the occurrence of harmful effects in the residents. The five components to stage one together provide a comprehensive indirect estimate of the likelihood of there being a health risk to residents.

The interpretation of the results of these studies is summarized on Table 2. Among the numerous possible combinations of results five important combinations are displayed on Table 3. The first level of interpretation of the combination of the results from the five studies is to infer a certain likelihood of health risk. It is important to recognize that the interpretations on Table 3 do not take into account the possibility of chemical interactions and the weight given to evidence of exposure.

Table 2: Interpretation of stage one study results

STUDY	RESULTS		INTERPRETATION
#1 Chemical analysis	-VE		Probably no health risk Interpretation of a definitive health study constrained
	+VE		Health risk possible
#2 Toxicity testing	-VE		Probably no health risk
	+VE		Health risk possible
#3 Animal health	-VE		Probably no health risk
	+VE		Health risk possible
#4 Worker health	-VE		Health risk very improbable
	+VE		Health risk possible
#5 Residents' reported health	-VE		Attitudinal problem is small
	+VE	i	in combination with -VE results above the problem is most likely attitudinal only.
		ii	in combination with +VE results above the problem may be attitudinal or physical or both

Table 3: Basis for the decision on whether a health risk exists, positive and negative results are shown for the five studies and the corresponding decision

		STUDY NUMBER (see text)					HEALTH RISK
		1	2	3	4	5	
COMBINATION of RESULTS	A	+	+	+	+	+	YES
	B	+	+	+	+	-	YES
	C	+	+	-	-	+	NO
	D	+	+	+	-	_	NO
	E	-	-	-	-	-	NO

Chemical toxicity may change with the interaction of chemicals. It is possible that workers are exposed to chemicals prior to interactions which take place within the dump following a period of time. Subsequently it might be these interacted chemicals to which residents are exposed.

It is also possible that despite weak evidence suggesting the presence of a health risk evidence may be produced in stage two showing significant exposure. In such a case this would possibly be sufficient evidence to support a definitive health study.

A few additional comments can be made about the five studies of stage one.

It can be seen that the greatest importance is placed upon the results of the worker study. However, the contribution of all studies is unique and should be considered as a set of studies which together furnish a comprehensive information base on which to decide upon the presence of a health risk.

Studies 1 and 2 define the problem in chemical terms. Studies 3 and 4 define the maximum health risk, all other factors being equal, in animals and man. This assumes that animals and workers have maximum exposure and that they are the most likely to manifest a health effect because they have experienced the longest time period since exposure. Study 5 provides a social and historical definition of the problem.

These studies can all proceed concurrently except Study 2 which needs to be preceeded by Study 1. None of these studies are long term and could probably be completed within a two year period given adequate resources.

Once studies 1 and 2 are complete the necessary information is in hand to proceed with stage two concerning assessment of exposure.

2. Stage Two: Is there evidence of a significant level of exposure among residents?

Stage two is of considerable importance because a health risk depends upon the residents having been exposed significantly to the toxins. Secondly, the exposure of individuals requires to be defined in order to identify the study group for follow-up in a definitive health study.

There are four components to the assessment of exposure.

A. Direct measurement: The first step is to measure human samples (blood, urine, secretions, fat) for the presence and concentration of the chemicals of interest. These analyses will be limited by necessity to those chemicals which remain in body tissues for prolonged periods such as pesticides, PCB's and heavy metals. These data may be provided on some individuals by the laboratory investigations ordered by the physician in the medical assessment as part of the study of residents' reported health. There will need to be a systematic study however of directly measurable body burdens of specific chemicals. This will need to be designed partway through stage one in order to avoid repeat laboratory testing unnecessarily.

B. Indirect measurement: There are at least four indirect measures of exposure which need to be considered. These measurements may help determine whether exposure was of a significant level. These four approaches are:

(i) Workers' laboratory tests
(ii) Animals' laboratory tests
(iii) Environmental pollution levels
(iv) Residents' history

Given the presumed high exposure of workers it would be expected that body burdens of toxins among the site workers would be greater than those of the residents. The workers' laboratory tests would therefore provide an indication of the upper limit to be expected in residents.

Wild animal body burdens would provide an index of a similar significance to those of the workers. It would be assumed that the wild animals living by the site would have the maximum possible exposure and thus the highest body burdens. If these were found to be low, the implication would be that the expected levels for residents would also be low or possibly insignificantly low.

Environmental testing suffers from the fact that the landfill has been closed and capped. These measurements therefore need to be interpreted with considerable caution.

The residents' histories of contact with the landfill and the pollution it causes may provide some insights into exposure but cannot be used to assess the extent of exposure.

C. General population exposure: A major difficulty in assessing chemical exposure arising from a particular source is the presence of multiple sources of chemical exposure. It is important to know the level of the chemicals of interest in the general population. Estimates of these levels may be obtainable from several sources which are readily available and require little added organization to obtain. Such sources include post mortem specimens, regional laboratory samples and hospital samples of urine, blood, hair and surgical specimens.

D. Assessment of other sources of exposure: The final dimension to the evaluation of exposure is the determination of other sources of exposure. This requires to be conducted at an individual level and estimates of exposure to the specific toxins require to be made by means of careful history taking.

From these investigations a decision needs to be made concerning the level of exposure the residents have experienced as a result of the landfill site.

3. Stage three: The health study

If either, stage one and stage two are positive, that is, there is evidence of a health risk and residents have been exposed significantly, or stage two is positive then the follow-up study is probably indicated.

This study would entail two components.

The first component would be a medical assessment of current health status of the study and control groups. This would entail a full medical examination to ascertain all major risk factors to health in general. It would also involve assessment of parameters of specific relevance to the toxins of interest. This investigation would be made under standard and controlled circumstances with particular attention paid to the quality of data.

The purpose of the medical assessment is to define the individuals' present state of health in terms of the outcomes of interest and to eliminate from the study all individuals in whom the outcomes are present. The second purpose is to define the similarity of the two groups in terms of all risk factors

(blood pressure, serum cholesterol, obesity) which are related to the outcomes of interest. Its purpose is not to determine whether the study group's health has already been affected by exposure to the landfill site.

The second component is the long term follow-up of the study group and control group over a period of approximately 20 years. This can be done through central statistics and does not require repeated contact with individuals providing the outcomes are major health events such as death or cancer.

E. Discussion: A strategy has been described which is a systematic stepwise approach to evaluating the health effect of a landfill site. The many unknowns concerning landfill sites preclude a simple single-stepped approach. In addition to the problem of defining the appropriate strategy there is the added problem of misinterpretations being made of the data which is collected. For these reasons the strategy needs to pay particular attention to both the benefits which can be achieved as well as the generation of information which could be mis-read.

Three stages have been described without any commitment to necessarily proceeding to the third stage. This stepwise approach should be evaluated in terms of a number of considerations. First it should provide maximum protection to the residents. Second it should have a built-in control to avoid doing more than is justifiable. Third it should do more good than harm.

Based on these three considerations this strategy has been proposed as one worthy of critical review as a methodology for assessing the health effects of point sources of pollution.

F. Implementation: The comprehensive appraisal of the likelihood of a health risk will be based on the above five categories of data. The methodology and timing is particular to each study and therefore each will be considered separately.

Study #1: Chemical Analysis of Site and Health Risk

The chemical analysis of the landfill site is in progress. The results of the analysis will be used to define that health risk which can be inferred by the chemical analysis. It is anticipated that the report of the chemical analysis will provide the required information. On this basis no budget plan-

ning is indicated for this beyond the existing chemical analysis study protocol.

Study #2: Ames Testing of Selected Chemicals

This study will depend upon the findings of the chemical analysis and whether or not Ames testing has already been done on the chemicals of interest. Planning for this study will therefore be scheduled to follow the receipt of the final results of the chemical analysis study. No budget is indicated at this time.

Study #3: Animal Study

In general there are four possible approaches to investigating the health effects upon animals. These are observational studies of:

i) wild animals, or of
ii) domestic animals; or experimental studies of
iii) animals placed on the site, or of
iv) laboratory animals exposed to selected chemicals of interest.

There are strengths and weaknesses of each approach which need to be considered prior to selecting the most appropriate method.

In order to appraise the appropriate methodology a veterinary epidemiologist is required. It is proposed that such a person be consulted for this purpose (included in Bridging Budget). It is estimated that this task can be completed within a two month period and would require fifteen working days for the task.

The report from this consultation would be the basis for deciding upon the animal study(s) to be conducted. Following review of the report a submission would be made to facilitate implementation of the selected study(s).

Study #4: Worker Study

The proposed worker study is a comparative historical cohort analysis of the forty-three identified landfill site workers. The purpose of this study is to identify whether the reported health of these workers indicates that a difference in health risk exists between the landfill workers and matched workers.

The first step in this study is the design of the research protocol which will take four months to complete with the assistance of an experienced research assistant and secretarial support (included in Bridging Budget). It is anticipated that the minimal staffing for the whole project would be one research assistant full time and one secretary half-time for 12 months. A final budget including equipment, services, travel and staff will be submitted upon completion of the protocol.

Study #5 : Residents' Survey

The budget for questionnaire development and testing, development of the medical assessment procedure and the interview procedure is included in the Bridging Budget. The provisional budget and protocol for the residents' survey are presented in detail in Part III.

A proprotion of the assessment of exposure, as defined in Stage Two, will form part of some of the health risk studies. Once these protocols are complete a protocol for the assessment of exposure will be written. If additional budget items are required this budget will be submitted in the Fall of 1982.

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PART III:

A PROTOCOL

FOR A QUESTIONNAIRE SURVEY

OF

RESIDENTS REPORTED HEALTH

A.

McMASTER UNIVERSITY
HAMILTON, ONTARIO, CANADA
Faculty of Health Sciences

SUBCOMMITTEE ON THE ETHICS OF
RESEARCH IN HUMAN EXPERIMENTATION

A local committee consisting of:

Professor	Psychiatry
Assistant Professor	Pathology and Medicine
Associate Professor	Family Medicine
Assistant Professor	Anaesthesia
Assistant Professor	Clinical Epidemiology and Biostatistics and Medicine
Assistant Professor	Clinical Epidemiology and Biostatistics
Assistant Professor	School of Nursing
Associate Executive Director	Administration
Manager	Committee on Scientific Development
Lay Member	

has examined the projected titled: Upper Ottawa Street Landfill Site Health Study.

as proposed by: A.C. Harper and H.L. Nelson

and have found it to meet our criteria of acceptability on ethical grounds. This review has been conducted with a view to insuring that the rights and privacy of the subject have been adequately protected; that the risks of the investigation do not outweigh the anticipated gain; and that informed consent will be appropriately obtained.

Date: May 1, 1982

For the Committee

B. Brief Description of Proposed Research

A comparative cross-sectional survey is proposed to address the question of the effect of the landfill site upon the health of nearby residents. A group of 1150 residents living within 1 kilometer of the landfill will be selected and their reported health, as measured by both interviewer and self-administered questionnaires will be compared with the reported health of a group of 1150 individuals residing in matched residential areas not in proximity to a dump site. Outcome measures include social, emotional and physical health, health perceptions, disability days, and health services utilization.

It is expected that the study will take 18 months to complete.

D. PROPOSAL

1. Objectives

The purpose of the study is to define the reported health status of residents in the vicinity of the Upper Ottawa Street landfill site. The findings of a small study suggested that the residents were experiencing more health problems than expected and due to concern about this possibility this survey has been designed to assess systematically the reported health of residents. The specific aims are:

(1) To identify whether residents in the vicinity of the landfill site report an excess of health problems.

(2) To determine whether there is an association between health problems and the proximity of residence to the site or duration of residence in the locality.

(3) To define qualitatively the types of health problems reported by the residents and to compare these with the problems reported by the comparison group.

2. Present State of Knowledge

The Upper Ottawa Street landfill site covers an area of approximately one hundred acres within which waste materials form an 85 foot high mound covering 40 acres. The site was closed in October 1980. It had been used for over 30 years with maximum usage taking place during the 1970's when up to five million gallons of liquid industrial waste were deposited annually. The contents of the site are not contained within it due to fractured bedrock under the site and the presence of the Red Hill Creek flowing through the site.

As has been described above ("A Strategy to Assess the Health Effects") the evidence is inadequate and incomplete concerning the harmful effects of landfill sites in general and this site in particular. The lack of knowledge is a major problem for which a comprehensive strategy is required. This survey forms one part of the proposed strategy.

At this time the public health issue to be addressed is one of public concern about the possible harmful effects of the landfill. In order to decide upon a policy to respond to the concern it is necessary to define the underlying problem. No well-defined health problem has been reported and therefore no focus exists for investigation. The residents themselves have drawn attention to their own symptoms. In order to respond appropriately it

is necessary to define the residents' reported health in a systematic manner and to assess what type of problems should be the focus of further investigation.

The importance of clarifying the nature and extent of the residents' perceived problems is heightened by the complexity and difficulty of investigating the causative relationship between the landfill site and health. One of the major effects of chemical exposure is the increase of cancer risk. However this has been demonstrated in man when exposure is of a high level. The effect of small exposures is not known. Furthermore the time lag between exposure and the increased occurrence of cancer is in the order of 20 years. Even when cancer is diagnosed there is the problem of knowing which source of toxic exposure was responsible. In industrial society multiple sources of chemical exposure exist and in the case in point there needs to be a method for distinguishing between the effect of the landfill site and other sources of chemical exposure. For all of these reasons the decision to investigate the health effects of a landfill site should be well founded. Preliminary investigations are therefore of major importance both in justifying a definitive investigation and in deciding what health effects warrant investigation.

Relevant Work of Applicants

Dr. Harper is an epidemiologist trained in public health. He has been a consultant to the Upper Ottawa Landfill Site Project since September 1981 and has conducted a feasibility study into the methodology of investigating the health effects of the site. Mr. Nelson is a methodologist who has been the research associate on the feasibility study. Prior to this he was involved in an international community health project in West Africa which involved considerable responsibility under difficult circumstances

3. Research Design

The research design is a comparative cross-sectional survey of residents who reside in the vicinity of the Upper Ottawa landfill site. These residents will be compared with a control community which is not near a landfill site and which has been matched on demographic characteristics. Data on health and contact with toxins will be collected by both questionnaire and interview.

4. Selection of the Study Population

(a) Description of the study area

The initial criterion for the selection of the study group is defined in terms of geographic distance of residences from the landfill site. The study group will be selected from individuals who reside in dwelling units situated within one kilometre from the current perimeter of the landfill mound. Secondly, eligible individuals must have resided within this distance limit at the time of the 1980 property tax assessment done in September, 1980. This time point conveniently precedes the date when the site was closed by one month, October 1980. The outer dark line on the following map (Figure 1) approximates the included area. Areas further than one kilometre along the Red Hill Creek in lower Hamilton have not been included because of the difficulty in differentiating the contribution of the landfill site to the water pollution of the creek (1) and to the air pollution of lower Hamilton. At this stage of investigation, when evidence indicative of a health risk is being sought, there does not appear to be an indication to expand the breadth of study beyond the residential area defined above.

The Planning Department of the Regional Municipality of Hamilton-Wentworth define sixty-five "planning units" (previously known as "neighbourhoods") on the mountain in Hamilton and Stoney Creek. The landfill is situated in Trenholme; eight other planning units, one of which is unpopulated, border on Trenholme. The population growth of these planning units from 1972 to 1980 is shown in Table I, and the age and sex distributions in Tables II and III.

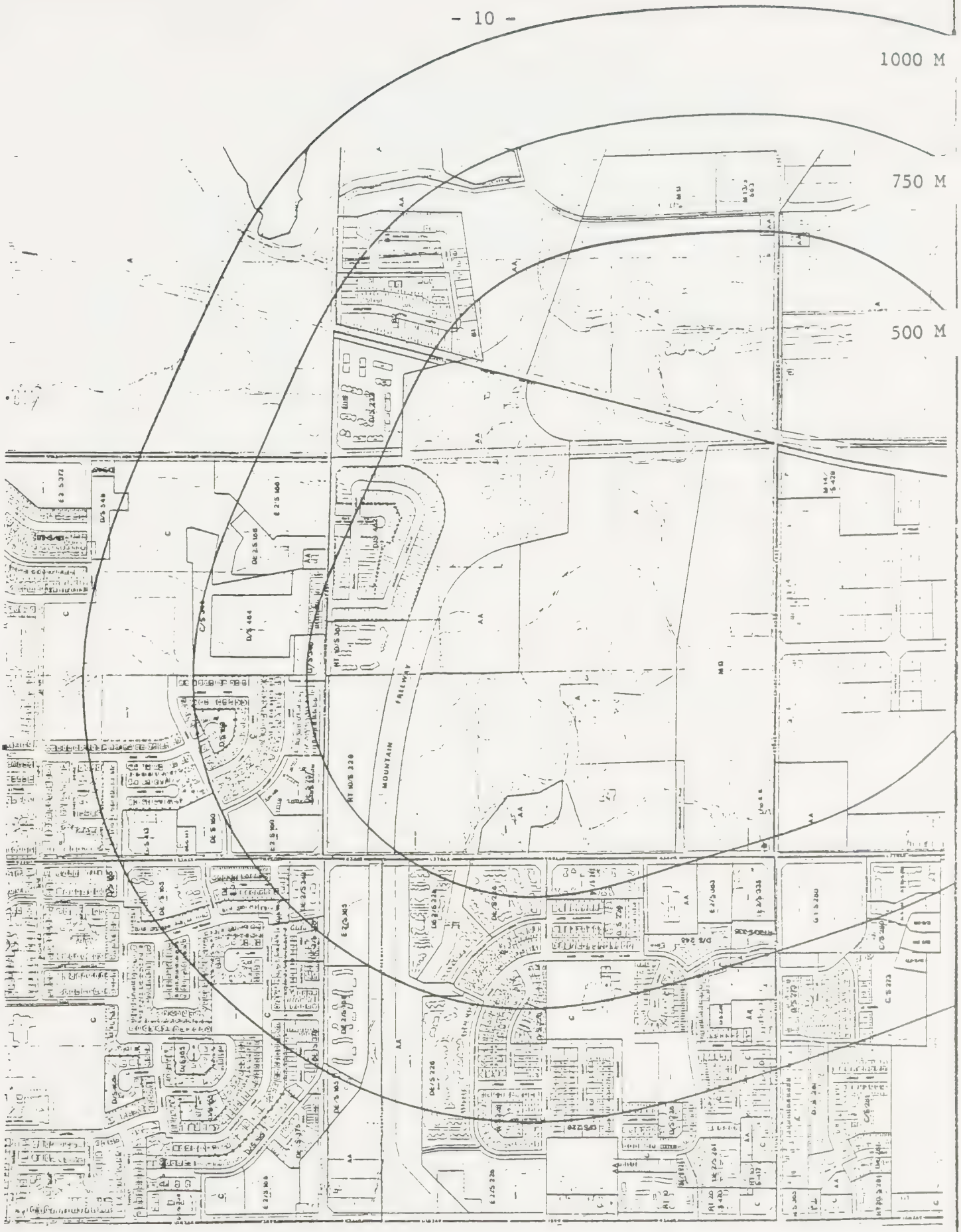

FIGURE 1: Map of the area surrounding the landfill showing three geographically defined strata.

Table I: Population Growth by Year and Planning Units Adjacent to Landfill Site

	Planning Unit							
	Berris-field	Lisgar	Quinn-dale	Tren-holme	Albion Falls	Temple-mead	Rymal	North Hannon
1980	4106	2722	3013	585	294	1083	12	69
1979	3967	2535	2800	541	280	1040	29	79
1978	3861	2458	2799	511	233	956	45	78
1977	3773	2204	2196	559	192	876	53	79
1976	3653	2044	1533	392	135	761	56	85
1975	3439	1938	958	176	135	452	71	92
1974	3413	1884	645	14	156	148	76	96
1973	3247	1509	99	15	167	163	95	96
1972	2031	927	119	18	187	164	129	97

Table II: 1980 Population by Age and Planning Units Adjacent to Landfill Site

	Planning Unit							
	Berris-field	Lisgar	Quinn-dale	Tren-holme	Albion Falls	Temple-mead	Rymal	North Hannon
0-4	297	233	356	81	19	130	-	5
5-13	779	527	685	133	57	198	-	11
14-18	472	288	231	26	23	84	2	5
19-25	407	275	289	57	46	118	2	8
26-40	1039	702	1023	215	62	377	2	12
41-64	863	529	323	54	71	145	5	23
64+	204	69	32	7	9	13	1	1
unknown	45	99	74	12	7	18	-	4
Total	4106	2722	3013	585	294	1083	12	69

Table III : 1980 Population by Sex and Planning Units Adjacent to Landfill Site

	Planning Units							
	Berris-field	Lisgar	Quinn-dale	Tren-holme	Albion Falls	Temple-mead	Rymal	North Hannon
Males	1981	1324	1480	264	155	538	6	34
Females	2080	1299	1459	309	132	527	6	31
Unknown	45	99	74	12	7	18	-	4
Total	4106	2722	3013	585	294	1083	12	69

(b) Selection of control areas

The comparison group for this study will be selected on the basis of certain residential and demographic similarities to the study group. While this matching may reduce the generalizability of the results of this study to the general population, it should make the distribution of potentially confounding variables more comparable in the two groups.

Characteristics of planning units adjacent to the landfill will be compared with other planning units, and the sampling frame will be derived from the most similar planning units. The following considerations will be used in selecting eligible comparison planning units:

(i) Location within city.

Planning units in the lower city and those on the mountain brow are excluded. An ongoing study of air pollutants in Hamilton has evidence of differences between the lower city, the mountain brow, and the rest of the mountain. (2)

(ii) Proximity to other dump sites.

Selected planning units may not contain old dump sites, whether domestic or industrial. The Ministry of the Environment has completed a survey of all known and rumoured sites in Ontario. The presence of a known or rumoured site within or adjacent to a neighborhood would disqualify that neighborhood.

(iii) OHC involvement in development.

Some of the development of housing in the planning units, adjacent to the landfill was organized by the Ontario Housing Corporation. This programme involved the selection of purchasers by such criteria as income and family size from a large pool of applicants. Comparison neighbourhoods will contain similar proportion of housing from the same programme.

(iv) Proportion of physical land use.

Both the proportion of physical land use (residential, commercial, industrial) and the proportion of residential land use (townhouses, apartments, detached houses, etc.) will be considered in the selection of comparison neighbourhoods.

(v) Mean assessed value per dwelling unit.

Consideration will be made of assessed value of housing in each planning unit. Criteria for assessment are uniform within Hamilton.

(vi) Parallel development and population growth.

The area around the landfill site was primarily farmland until the early 1970's. The housing developments are thus recent and the population possibly different in some respects from the population of older areas of Hamilton.

(vii) Age and sex distributions.

Age distributions indicate that the planning units adjacent to the landfill site have a younger population than the general population of Hamilton. Following the application of exclusion criteria, the age distribution (10 year age categories) of women in eligible planning units will be compared to those of the planning units adjacent to the landfill, using goodness-of-fit techniques. The planning unit most similar to each planning unit adjacent to the dump will be selected.

Population growth, assessed value, OHC involvement in development, and physical land use are likely to be closely interrelated. The specification of the procedures for including or excluding planning units is described further in D.6. b.(ii).

(c) Sampling

(i) Sampling techniques

A sampling frame for each selected planning unit will be developed from the property tax data base, the study planning units will be further broken

down by distance of residence from the landfill within the following strata: less than 500 metres, 500 to 750 metres and 751 to 1000 metres. (See Figure 1) A sampling fraction will be derived from the sample size required and the total number of eligible individuals. A simple random sample will be drawn from each strata of the study group and each planning unit of the comparison group.

In addition, all eligible individuals residing in the first stratum (less than 500 metres) will be selected for interview. This subgroup has been included for the purposes of hypothesis-generating only and will not be included in the major analyses except where the same individuals were selected in the stratified random sample.

(ii) The sampling frame

The sampling frame comprises women 18 years of age or older who reside within the three strata of the study area or within the selected comparison planning units. The reasons for sampling women are based on the following assumptions:

(a) mothers are assumed to be the most informed with respect to the health of their children,

(b) women are assumed to be the most reliable informants with respect to the reproductive endpoints measured in this study,

(c) women are assumed to have less occupational exposure to the industrial waste known to have been dumped in the landfill.

Permission to access the property tax assessment data base has been requested of the City of Hamilton. This data base contains the necessary information for the identification and location of individuals required for the sampling frame.

5. Measurement

a. Measurement instrument development

Data will be collected using both personal interview questionnaires and self-administered questionnaries. Whenever possible, previously standardized and validated questionnaires or portions of questionnaires will be used to reduce time required for development and pretesting. Where applicable, the items and format from the Canada Health Survey (4) will be chosen over other alternatives so as to permit comparisons with the general population of Canada.

Table IV lists the components to be included in the questionnaires. In general, those items which require probing or interpretation will be included in the interview format and will be collected for the entire household from the selected respondent, and items which may be sensitive or could only be answered reliably by the individual involved will be included in self-administration format.

Table IV: Components of the Questionnaire

1. Demographic data

a) address
b) type of dwelling
c) age (all family members)
d) sex (all family members)
e) occupation (all family members)
f) marital status
g) family size
h) ethnicity
i) name of family physician

2. Landfill site exposure history

a) residential history
b) type of contact: (i) residential
(ii) direct occupational contact
(iii) direct recreational contact
(iv) indirect contact via vegetable gardens, wells, etc.

3. Exposure-related confounders

a) occupational history
b) recreational/domestic use of chemicals
c) exposure to other landfill sites

4. Outcome-related confounders

a) current medications
b) alcohol use
c) tobacco use
d) other drug use
e) pre-existing medical conditions
f) medical history
g) family medical history
h) accidents

5. Outcomes

a) chronic health problems
b) symptoms review
c) dental, hearing, vision
d) physical health
e) emotional health
f) social health
g) health perceptions
h) reproductive history
i) disability days
j) health services utilization

Questionnaires which will likely be used in whole or in part for the development of the instruments for this study are listed below; copies of these questionnaires (or relevant portions) are included in Appendix A.

(1) Canada Health Survey (3)

  (a) Interviewer Administered Questionnaire
  (b) Lifestyle and Your Health Questionnaire

(2) Bradburn's Affect Balance Scale (4)

(3) MacMillan's Health Opinion Survey (5)

(4) McMaster Health Index Questionnaire (6,7)

(5) Epidemiology Standardization Project - Pulmonary Disease Questionnaire (8

(6) Children's Respiratory Health Study Questionnaire (9)

(7) Rand Corporation, Health Insurance Study

  (a) Current Mental Health Battery (10)
  (b) Social Health Battery (11)
  (c) Health Perceptions (12)

(8) Neuro-psychological Questionnaire (13)

A draft of the questionnaires compiled for use in this study will be pretested initially on a small group of volunteers to obtain feedback on clarity, acceptability and interview flow. A second pretest will be done on a small sample of individuals with similar demographic characteristics to the study and comparison groups, but who reside outside the selected survey areas.

The interview questionnaire will be administered by trained epidemiologic interviewers. Interviewers will be randomly assigned respondents in both study and comparison areas.

b. Sample size calculations

The formula from Colton (14) for the determination of sample size for the comparison of two independent proportions and the prevalence of health problems from the Canada Health Survey (3) have been utilized to produce Table V. These are the sample sizes required to detect a difference of 50% in one-tailed tests with $\alpha = 0.05$ and $\beta = 0.10$.

Table V: Sample size calculations

Canada Health Survey Health Status	Canada Health Survey Rates for women over 15	Required Sample Size per group
No health problem	.341	283
Headache	.089	751
Acute respiratory Bronchitis + emphysema Asthma	.083	810
Disability Days (proportion of year)	.060	1180
More than 10 MD consults in past year	.142	449
Positive Affect Balance	.442	190
Negative Affect Balance	.052	1374
Infrequent symptoms of anxiety and depression	.910	22
Frequent symptoms of anxiety and Depression	.055	1251

Note: The means and standard deviation for disability days and number of MD consults were not conveniently available for sample size estimates for continuous data. It is most likely that the sample size required for these two measures at the above stated levels would be substantially smaller.

A sample of 810 individuals per group would be required to detect a 50% increase in the frequency of individuals with acute respiratory problems. Conversely, if one assumes 800 individuals per group, the detectable difference and direction of change at the same α and β levels are shown in Table VI.

Table VI: Detectable differences given a sample size of 800

Canada Health Survey Health Status	Canada Health Survey Rates for Women over 15	Detection Occurs at:	% Change
No health problem	.341	.273	-25%
Headache	.089	.133	+49%
Acute respiratory Bronchitis + emphysema Asthma	.083	.125	+51%
Disability Days (proportion of year)	.060	.097	+62%
More than 10 MD consults in past year	.142	.195	+37%
Positive Affect Balance	.442	.370	-19%
Negative Affect Balance	.052	.086	+65%
Infrequent symptoms of anxiety and depression	.910	.866	- 5%
Frequent symptoms of anxiety and depression	.055	.091	+65%

To allow for a response rate of 70%, 1150 individuals will be sampled from the study area and 1150 from the comparison area to obtain the stated levels.

6. Procedures

a. Interviewer training

Interviewer training procedures will include handout materials, lecture/seminar sessions on interview techniques, role-playing under supervision using the questionnaire to ensure standardized presentation, and detailed item-by-item review of the final version of the questionnaire.

b. Sampling and Selection Procedures

(i) Selection Stratification of the Study Area

The study area is defined as the area within 1 kilometre of the current perimeter of the landfill mound, and three strata have been defined as the areas within 500 metres, 501-750 metres, and 751-1000 metres of the perimeter The perimeter will be defined by overlaying transparencies of aerial photographs of the site on to the residential map of the area (City of Hamilton, 1: 5000, Sheet 7, available from the Regional Planning Department). Arcs of radius 10, 15 and 20 centimetres, corresponding to 500, 750 and 1000 metres, will be drawn from points on the perimeter and joined by a smooth curve.

Addresses within each stratum will then be listed. Those properties cut by the dividing line will be included in the "closer" stratum, for example, a property out by the 750 metre line is included in the 501-750 metre stratum, a property cut by the 1000 metre line is included in the 751-1000 metre stratum. Those properties wholly outside the 1000 metre lines are not included in the study area. The lists of addresses within strata will be used for the selection of study individuals as described in B. (iii) and (iv).

(ii) Selection of comparison areas

Selection of comparison areas will be made on the basis of similarities along specified dimensions to the area surrounding the landfill site. Portions of nine planning units are included in the study area, one is unpopulated, two more have populations of 12 and 69 and may not be able to be matched to comparison areas exactly as prescribed below. Planning units not on the mountain brow are excluded from further consideration. Planning units which contain or are adjacent dump sites listed in the Ministry of Environment survey of known and rumoured sites are also excluded.

The standard deviations of the following data will be calculated on the remaining (approximately 43) planning units:

(a) mean assessed value per dwelling unit
(b) proportion of physical land use for single detached dwellings
(c) proportion of physical land use for duplexes
(d) proportion of physical land use for townhouses
(e) the population increase from 1974 to 1980

The eligible comparison planning units for each study area planning unit are those which have the same OHC development status.
and which do not differ by more than one standard deviation from the mean of that study area planning unit.

Finally, the eligible comparison planning unit whose 1980 age distribution best fits the 1980 age distribution of the study area planning unit will be selected using χ^2 goodness-of-fit techniques. These procedures will be repeated for each study area planning unit.

(iii) The sampling frame

The names and addresses of all women 18 years of age and older on the 1980 property tax assessment database within each of the selected planning units will be listed in sequentially numbered computer files generated from the tax assessment database and the stratification map described previously.

(iv) Sampling

The sampling fraction will be derived from the sample size required and the total number of eligible individuals abailable in the study area. The total number of eligible individuals in each comparison area planning unit and each study area stratum will be multiplied by the sampling fraction to determine actual numbers of individuals required from each of these sub-areas. A computerized random number generator will be used to select the required number of individuals from the sequential list of names for each sub-area. This final list of names and addresses within strata and planning unit identifies the study population.

c. Notification

After the interview and questionnaire forms and procedures are finalized, a letter of introduction to the selected respondents will be devised. The letter will contain:

(i) an introduction of the project coordinator and the Department of Clinical Epidemiology and Biostatistics,

(ii) an invitation to request further information from the project coordinator, if desired,

(iii) notice to expect a telehpone request for scheduling of the home interview,

(iv) a brief description of the home interview and of the self-administered questionnaire,

(v) assurances of the confidentiality of all data collected, and

(vi) a reminder of the voluntary nature of participation.

The letter of introduction will be mailed to each selected respondent. Interviewers will be responsible for scheduling home interviews with their assigned respondents and for leaving the self-administered questionnaire and a stamped, addressed envelope with the respondent at the end of interview. Up to four callbacks will be made for missed interviews.

d. Maintaining compliance

In the event that the interviewer is missed by the respondent, up to four callbacks will be made.

The interviewer will leave the self-administered questionnaire form with the respondent at the end of the interview with brief instructions and a request for continued cooperation. The study centre will telephone reminders to the respondent every two weeks until the questionnaire is received, a refusal obtained or a maximum of four call have been made. Additional forms will be mailed to the respondent if needed.

7. Data Management

a. Data Acquisition

Data collection forms and coding forms will be designed for both the self-administered questionnaire and the interview. These forms will be used for the pretest and will be modified as needed after each stage of pretesting.

At the end of the interview, the interview form will be edited for completeness and consistency by the interviewer. At that time, the interviewer will leave the self-administered form with a stamped, addressed envelope.

The interviewer will be responsible for delivering interview forms to the study centre.

b. Data entry

Data collection forms will be coded by study centre staff, then key-punched and verified by keypunching staff at the Health Sciences Centre Computational Services Unit (CSU).

Data will be entered and maintained on the CSU HP3000 computer. A locally written and supported data management program called GETSPSS will be used to manage data.

c. Managing data flow

An interactive forms management system will be devised using QUICK and QUIZ (15) on the HP3000. Each of the following transactions will be recorded immediately following their occurrence for each study participant:

(i) letter of introduction mailed
(ii) telephone calls for scheduling interview
(iii) scheduled date of interview
(iv) interview refused
(v) interview forms recieved
(vi) questionnaire froms delivered
(vii) telephone reminders
(viii) forms sent to coding
(ix) forms returned from coding
(x) forms sent to keypunching
(xi) forms returned from keypunching
(xii) data entered onto computer
(xiii) erroneous data returned by editing programs
(xiv) correction update complete.

With this system, status reports on any individual or sub-group can be generated at any time. Study progress reports, work assignments and schedules, missing data reports and other reports will be generated by the system on both a regular and an ad hoc basis.

d. Data integrity and security

Range and valid value checks will be done on data files at the time of entry or update. Erroneous data will be referred back to research staff for

correction.

On two occasions, after about 10% of the data have been collected, and again after 100%, a small random sample of forms will be recoded, repunched and re-entered and compared with the originals to estimate error rates.

A 10% sub-sample of respondents will be telephoned following the home interview and re-asked two of the home interview questions. This data will be compared with the original and used to estimate reliability.

A system of passwords which will be changed at intervals will be used to restrict access to the database to authorized research personnel.

A tape rotation archiving system will be used to ensure the integrity of the data from accidental or unauthorized destruction. New tapes will be inserted in to the rotation at regular intervals. Backup tapes will be stored both at the CSU and off-site. In addition, the original data forms, coding forms and punched cards will be retained until the end of the study.

8. Data Analysis

Analysis of the data will be performed using subprograms in either Biomedical Computer Programs (16) or the Statistical Package for the Social Sciences (17). Most of the data is categorical in nature; for simple contingency tables, χ^2 analyses will be done, to examine the relationship of potentially confounding variables to exposure and outcome, discreet multivariate analysis will be required using log-linear models. For continuous data, t-tests and multiple regression will be used. Descriptive statistics such as means and frequencies of demographic data will also be calculated on both groups.

As mentioned in the sample size section α has been set to 0.05, β to 0.10, both one-tailed. It is anticipated that each outcome will be challenged as many as three times, to test the relationships of group, confounders and "dose-response" in the study group. To adjust for these multiple challenges, probability values less than 0.017 will be labelled "*statistically significant*", values between 0.017 and 0.05 will be labelled "*interesting, worthy of further study*", values greater than 0.05 will be labelled "*not important*".

9. Ethical Considerations

The ethical considerations relate to confidentiality and referral to the individual's family physician.

All interview and questionnaire data will be confidential. The interviewees will be informed of this. The purpose of the study will be described in writing which the interviewee will receive prior to being telephoned to make an interview appointment. A consent form will be signed at the time of interview. A second signature will be requested for permission to send a summary of the data to the individual's personal physician.

In the written information and telephone contact the individual will be informed of their right to refuse and that there will be no personal consequences of not participating.

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APPENDIX A

SOURCE QUESTIONNAIRES

Oxford
1588
MADE IN CANADA